SCIENTIFIC COOPERATION

Medicine and Public Health

Protocol Between the
UNITED STATES OF AMERICA
and CHINA

Signed at Beijing December 4, 2008



NOTE BY THE DEPARTMENT OF STATE

Pursuant to Public Law 89—497, approved July 8, 1966 (80 Stat. 271; 1 U.S.C. 113)—

"...the Treaties and Other International Acts Series issued under the authority of the Secretary of State shall be competent evidence... of the treaties, international agreements other than treaties, and proclamations by the President of such treaties and international agreements other than treaties, as the case may be, therein contained, in all the courts of law and equity and of maritime jurisdiction, and in all the tribunals and public offices of the United States, and of the several States, without any further proof or authentication thereof."

CHINA

Scientific Cooperation: Medicine and Public Health

Protocol signed at Beijing December 4, 2008; Entered into force December 4, 2008.

PROTOCOL BETWEEN THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES OF AMERICA AND

THE MINISTRY OF HEALTH OF THE PROPLE'S REPUBLIC OF CHINA FOR

COOPERATION IN THE SCIENCE AND TECHNOLOGY OF MEDICINE AND PUBLIC HEALTH

The Department of Health and Human Services of the United States of America and the Ministry of Health of the People's Republic of China (hereinafter referred to as "the Parties"), for the purpose of promoting cooperation and the exchange of information in the field of health,

Recognizing the importance of progress in the health sciences and health administration for the quality of life for all people;

Desiring to fully share advances in the field of health of benefit to the peoples of both countries;

Desiring to continue strengthening the friendly relations between the peoples of the two countries; and

Recognizing the benefits both Parties derive from close, continued cooperation in these fields begun under the Protocol for Cooperation in the Science and Technology of Medicine and Public Health, signed on June 22, 1979, as extended and amended;

Have agreed as follows:

ARTICLE I

1. This Protocol is subject to and governed by the Agreement between the Government of the United States of America and the Government of the People's Republic of China on Cooperation in Science and Technology, signed on January 31, 1979, as amended and extended (hereinafter referred to as the "Science and Technology Agreement").

- 2. The Parties shall promote cooperation between the two countries in disease control and prevention; the supervision and regulation of health-related products, such as food and cosmetics; health protection; biomedical research; health-care and health-policy research; and health administration and finance.
- 3. The principal objectives of the cooperation are for both Parties to provide each other opportunities to exchange ideas, information, skills and techniques, and to collaborate on problems of mutual interest.

ARTICLE II

The cooperation contemplated in this Protocol (hereinafter referred to as "the Health Protocol") may include exchanges of scientific, technical, and health-systems management information; exchanges of scientists and technical experts; the convening of joint seminars and meetings; the conduct of joint research projects; and other forms of health-related scientific and technical cooperation as both parties may mutually agree.

ARTICLE III

Pursuant to the aims and provisions of this Health Protocol, the Parties shall encourage and facilitate the development of direct contacts and cooperation between constituent agencies and scientists of the two Parties, and universities, research centers and other institutions of the two countries. Under this Health Protocol, the Parties may agree to co-sponsor cooperative activities in the fields of health and biomedical research with other agencies of the Governments of the United States and the People's Republic of China. The Parties shall describe each such activity in writing, with the agreement of both Executive Agents (see Article V, below).

ARTICLE IV

1. The Parties shall coordinate joint activities, where possible, with, or make them supportive of, the activities and goals of international health bodies, including the World Health Organization.

2. The Parties may invite scientists, technical experts, Governmental agencies and institutions of third countries or international organizations, in appropriate cases, to participate, at their own expense (unless otherwise agreed), in projects and programs being carried out pursuant to this Health Protocol.

ARTICLE V

1. To assist in the coordination of activities, to facilitate cooperation, and to provide guidance, as needed, the Parties designate the following "Executive Agents" for each side:

For the Chinese Ministry of Health:

Director-General
Department of International Cooperation

For the U.S. Department of Health and Human Services:

Director Office of Global Health Affairs Office of the Secretary

- 2. The Parties shall conduct cooperative activities under this Health Protocol in accordance with all applicable laws and regulations in both countries, subject to the availability of funds and personnel.
- 3. Each organization that undertakes cooperative activities and scientific collaboration pursuant to this Health Protocol shall be responsible for its own costs for its activities, unless otherwise mutually agreed upon, in writing. For official visits under this Health Protocol, unless otherwise agreed upon, in writing, the sending side shall provide for, or cover the costs of, the international and internal transportation, lodging, and per diem expenses of its delegation.
- 4. Either Party may propose activities to carry out under this Health Protocol, may documented in work plans or other written correspondence, to establish mutual, written agreement, in advance of each activity.

- 5. To protect human subjects involved in research, before the Parties initiate any project that involve human subjects, the Executive Agents shall be responsible for promoting compliance with appropriate international guidance, recognized as such, by both countries. The Executive Agents shall be responsible for ensuring that any project or activity carried out pursuant to this Health Protocol and that involves human subjects is in compliance with the applicable laws and regulations of the Parties.
- 6. To protect the welfare of laboratory animals and endangered species, the Executive Agents shall be responsible for promoting compliance with appropriate, international guiding principles recognized by both Parties, for biomedical research that involves animals. The Executive Agents shall be responsible for ensuring that any project or activity that involves animals carried out pursuant to this Health Protocol is in compliance with the laws and regulations of the Parties applicable to the use of laboratory animals. In addition, both Parties shall comply with the provisions of the 1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora, with appendices, as amended.

ARTICLE VI

- 1. Neither Party shall provide any information or equipment identified as requiring protection for national-security reasons or foreign relations (such as that which is classified in accordance with national laws or regulations) under this Health Protocol. In the event the Parties discover that such information of equipment is known or believed to have been inadvertently created or furnished in the course of projects or cooperation under this Health Protocol, both sides shall protect it from unauthorized disclosure under the applicable laws, regulations and administrative practices of each Party. Where information or equipment has been or is believed to have been inadvertently disclosed to unauthorized recipients, the originating Party shall be informed immediately of the disclosure. The Parties shall consult to identify legal requirements and appropriate security measures, if any, to agree upon in writing, and apply then to this information and equipment, and shall, if appropriate, amend this Protocol to incorporate such measures.
- 2. This Health Protocol does not supersede the national laws and regulations of either Party with respect to transfers and release of information and equipment subject to export laws and regulations. If either Party deems it

necessary, the Parties shall incorporate into the written work plans for projects detailed provisions for the prevention of unauthorized transfer or retransfer of such export-controlled information or equipment. The Parties shall mark export-controlled information to identify it as "export-controlled" and to identify any restrictions on further use or transfer. The Parties shall mark such information or equipment to identify it as "export-controlled", and the Parties shall consult to identify appropriate restrictions or other requirements regarding the transfer of this information or equipment.

ARTICLE VII

- 1. The Parties shall use their best efforts to facilitate the entry to and exit from their territories of personnel and equipment of the other party engaged in or used in projects and programs under this Health Protocol.
- 2. Each Party shall agree, within its statutory or regulatory guidelines and authorities, to use its best effort to assist and expedite any clearances required for investigators from either Party in the exchange of biological materials necessary for research conducted under this health Protocol.
- 3. The Parties shall endeavor to ensure all participants in agreed cooperative activities under this Health Protocol have access to facilities and personnel within their countries, as needed, to carry out those activities.

ARTICLE VIII

The provisions of Annex I of the Science and Technology Agreement will govern protection of intellectual property created or furnished in the course of activities under this Protocol, the allocation of rights for such intellectual property, and business-confidential information obtained and/or exchanged pursuant to this Protocol.

ARTICLE IX

Nothing in this Health Protocol shall be construed to prejudice, limit, or determine other arrangements related to scientific and technical cooperation or assistance between the Parties.

ARTICLE X

- 1. This health Protocol shall enter into force upon signature, and shall remain in force for five years. The parties may amend, extend, or terminate it, by mutual written agreement.
- 2. The termination of this health Protocol shall not affect the validity or duration of any arrangements entered into pursuant to this Health Protocol prior to its termination.

Done at <u>Reijing</u>, China this <u>444</u> day of <u>December</u>, 2008, in duplicate, in the English and Chinese languages, both texts being equally authentic.

 FOR THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES OF AMERICA:	FOR THE MINISTRY OF HEALTH OF THE PEOPLE'S REPUBLIC OF CHINA:
Date: 12/4/08	Date: 4/12/2008

中华人民共和国卫生部和 美利坚合众国卫生与公众服务部 关于医学及公共卫生科学技术领域合作议定书

中华人民共和国卫生部和美利坚合众国卫生与公众服务部(以下简称"缔约双方"),为促进卫生领域的合作和信息交流;

认识到卫生科学及卫生管理进步对全体人民生活质量的重要性;

希望能充分分享卫生领域中有益于两国人民的进展;

希望能继续加强两国人民间的友好关系;

认识到自一九七九年六月二十二日签署并经修订和延期的《中华人民共和国卫生部和美利坚合众国卫生、教育、福利部医药卫生科技合作议定书》以来,缔约双方在这些领域里密切合作产生的利益;

达成协议如下:

第一条

- 一、本议定书根据经修订和延期的一九七九年一月三十一日签订的《中华人民共和国政府与美利坚合众国政府科学技术合作协定》(以下简称"科技协定")制定。
 - 二、缔约双方应促进两国在疾病控制和预防,食品、化妆品

等健康产品的监督管理,卫生保护,生物医学研究,卫生保健和卫生政策研究,以及卫生行政管理和财务方面的合作。

三、本议定书的主要目的在于为缔约双方提供交流观点、信息、技巧和技术的机会,并就缔约双方感兴趣的领域开展合作。

第二条

本议定书所指的合作可包括交流卫生科学、技术和卫生系统管理的信息,交换卫生科技专家,联合召开研讨会及各种会议,开展联合研究项目以及经缔约双方同意的涉及卫生领域的其他形式科技合作。

第三条

根据本议定书的目标和规定,缔约双方应鼓励和推动缔约双方和两国大学、研究中心及两国其他机构的有关部门和科学家之间进行直接联系与合作。在本议定书范围内,缔约双方可同意,中华人民共和国政府与美利坚合众国政府其他机构共同开展一些卫生及生物医学领域的合作活动。上述各项活动需书面提出并经第五条规定的缔约双方执行机构同意。

第四条

一、在可能情况下,联合开展的活动应能支持包括世界卫生组织在内的国际卫生机构的活动及目标或与其协调一致。

二、在合适的情况下,缔约双方可同意邀请第三国或国际组织的科学家、技术专家、政府部门及机构参加根据本议定书而开展的一些项目及规划,费用由其自行承担(除另有协议外)。

第五条

一、为有助于活动的协调,促进合作并提供必要的指导,缔 约双方各指定以下"执行机构",

中国卫生部:

国际合作司司长

美国卫生与公众服务部:

部长办公室全球卫生事务办公室主任。

二、本议定书范围内的合作活动,须根据两国适用法律和规章开展,并考虑缔约双方的人力及财力情况。

三、参与本议定书所述的合作活动及科学协作的组织应自 行负责其活动的经费,除缔约双方另有书面协议外。本议定书 内的正式访问,除另有书面协议外,派遣方将负担代表团的国 际、国内交通费用及每日食宿等费用。

四、缔约双方可就本议定书范围内开展的活动各自提出建议,并应在每项活动实施前拟定工作计划或其他缔约双方签订的书面文件。

五、为保护科研中所涉及的受试人,在开展任何一项涉及受试人项目之前,执行机构有责任促进这些活动符合两国承认的

国际指导原则。执行机构负责确保本议定书下开展的任何涉及受试人的项目或活动符合缔约双方有关的法律和规定。

六、为保护实验动物和濒危物种的生存条件,执行机构有责任促进有关活动要符合缔约双方都承认的相应的涉及动物的生物医学研究国际指导原则。执行机构要确保本议定书项下设计使用实验动物的任何项目或活动符合缔约双方有关的法律和规定。此外,缔约双方要遵守经修改的并有附录的一九七三年关于濒危野生动植物种类国际贸易公约各项条款。

第六条

- 一、本议定书范围内,任何一方不得提供由于国家安全原因或对外关系而需予保护的信息及设备(根据国家法律和规定被列入保密类的)。如果发现或认定在项目或合作执行过程中无意制造和提供上述的信息和设备时,应根据缔约双方各自国家的有关法律、法规和行政措施防止未经授权而披露。由于疏忽而向未经批准者披露或被认定披露上述信息或设备时,应在披露之时立即通知被披露方。双方应协商确定法律要求和适宜的安全措施,以书面形式同意并应用于上述信息和设备,而且双方应酌情在本议定书上增加上述措施。
- 二、本议定书不能代替各自一方国家根据出口法律及规定的有关信息、设备的转让和披露的本国法律及规定。若任何一方认为必要,应在项目的工作计划中写明有关防止未授权的出

口管制信息或设备的转让或再转让之具体条款。双方应为受出口管制的信息标识为"出口管制",并明确其进一步使用或转让的任何限制。双方应为上述信息或设备标明"出口管制",并且双方应协商制定有关该种信息或设备的适当限制措施或其他要求。

第七条

- 一、缔约双方应尽力帮助为参与本议定书开展项目活动的 人员和为供项目活动使用的设备办理出入境手续。
- 二、缔约双方同意根据各自国家的有关法律、规定和各自的权限,尽力帮助和加速在缔约双方科研人员所需求的根据本议定书开展的科研活动所必须的生物材料交换的过关手续。
- 三、缔约双方应努力确保向参与经商定的合作活动人员在需要时向他们提供使用本国设备和接触与活动有关人员的便利。

第八条

遵照科技协定附录一的规定,管理本议定书开展的合作活动所创造或提供的知识产权的保护、该种知识产权的权利分配、以及根据本议定书获取或交换的商业机密信息。

第九条

本议定书不损及、限制或影响决定缔约双方关于科技合作及援助活动的其他安排。

第十条

- 一、本议定书自签字之日起生效,有效期五年。任何对本议定书的修改、延长或终止,需要经过缔约双方的书面同意。
- 二、本议定书的终止不影响在终止前根据本议定书业已做出的任何安排的有效性和期限。

本议定书于二〇〇八年十二月 4日在北京签订,一式两份,每份均用中文和英文写成,两种文本同等作准。

中华人民共和国 美利坚合众国卫 生部代表 卫生与公众服务部代表

H 48